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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,026	04/09/2001	Michael Fox	1662/52302	8407

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/829,026	Applicant(s) FOX ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 01/08/02 and amendment filed 04/22/02. Claims 1-39 are pending and the claims were not amended in the amendment filed 04/22/02.

Claim Rejections - 35 USC § 102

1. Claim 1 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kreutter et al. (US 5,627,200).

Applicants' main argument in traversing the rejection is that Kreutter does not state that the composition does not contain another stabilizer or combination of stabilizers.

2. Applicant's arguments filed 04/22/02 have been fully considered but they are not persuasive. Kreutter does not teach the presence of another stabilizer in the composition.

Claim Rejections - 35 USC § 103

3. Claims 1-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kreutter et al. (US 5,627,200).

Applicants state that Examiner provided no motivation for the skilled artisan to modify the teachings of Kreutter to arrive at applicants' invention and that modifying Kreutter would mean that the artisan would forgo the use of β_3-adrenoceptor antagonist or agonist active agent.

4. Applicants' arguments filed 04/22/02 have been fully considered but they are not persuasive. The artisan does not have to forgo using **β_3-adrenoceptor antagonist or agonist** as active ingredient because the present claims do not exclude **β_3-adrenoceptor antagonist or agonist** in the composition. The claims merely recite active component that is a substituted dihydroxyheptanoic acid in the generic claim. Pravastatin and atorvastatin are recited in the

dependent claims. The difference between Kreutter and the application is in the amounts of the components in the composition. Specifically, Kreutter suggests the composition to comprise HMG-CoA reductase inhibitor. Contrary to applicants' assertion that examiner did not provide a motivation to modify Kreutter, it may be noted that the rejection on record presented why it would the invention is obvious over the prior art. A summary of the rejection is given below.

Kreutter discloses a composition comprising β_3-adrenoceptor antagonist or agonist (abstract, column 2, lines 12-18 and column 5, line 21), suitable pharmaceutical solid or liquid carrier or diluent to form capsules, tablets, powders, syrups, solutions and suspensions, additional optional components such as flavorants, sweeteners and excipients (column 19, lines 28-36), binders and disintegrants (column 19, lines 37-46), surfactants, sesame or peanut oil, ethanol, water or suitable mixtures thereof, N-methyl glucamine, polyvinylpyrrolidone and mixtures thereof (column 19, lines 60-66). The composition may also comprise HMG-CoA reductase inhibitor (lovastatin, simvastatin and pravastatin) and cholestyramine anion exchanger (column 26, lines 15-20). Kreutter discloses method for treating intestinal motility disorders, intestinal ulcerations, inflammatory bowel disease, ulcerative colitis, Crohn's disease and proctitis, and gastrointestinal ulcerations, depression, prostate disease and **dyslipidemia** by administering the said composition (abstract and column 2, lines 12-18).

The generic claim of the invention broadly teaches a composition comprising an HMG-CoA reductase inhibitor, amino-group containing polymeric compound (cholestyramine) and amido group containing polymeric compound (polyvinylpyrrolidone), Kreutter is silent on the amounts the components of the composition. And determination of the ranges of the amounts of the components of the composition is within the purview of the skilled artisan and the scope of

the broad range of components taught in the dependent claims may be encompassed in the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Kreutter. One having ordinary skill in the art would have been motivated to prepare the composition of Kreutter and administer it to a person in need thereof to treat intestinal motility disorders, intestinal ulcerations, inflammatory bowel disease, ulcerative colitis, Crohn's disease and proctitis, and gastrointestinal ulcerations, depression, prostate disease and **dyslipidemia.** Determining the amounts of the parts of a composition is within the purview of the skilled artisan to do and therefore obvious absent evidence in unexpected results to the contrary. Future intended use is not critical in composition claims.

5. Claims 1-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tsujita et al. (US 5,627,375).

Applicants ague that Tsujita does not teach that the composition does not contain another stabilizer or combination of stabilizers and that Tsujita teaches away from the invention in that the prior art discloses that the combination of two lipid regulating agents, pravastatin and cholestyramine is not sufficient to control hyperlipidemia.

6. Applicants' arguments filed 04/22/02 have been fully considered but they are not persuasive. Tsujita does not teach a composition that has another stabilizer or combination of stabilizers. Secondly, applicants are arguing about limitations that are not recited in the claims and the present claims are not directed to compositions that have both pravastatin and cholestyramine. And the future intended use of a composition is not critical to composition claims. The motivation to use the teachings of Tsujita is given in the rejection on record and the rejection is summarized below.

Tsujita discloses a composition comprising HMG-CoA reductase inhibitor (pravastatin, lovastatin, simvastatin, fluvastatin, rivastatin and atorvastatin), insulin sensitizers, vehicles, lubricants, binders, disintegrants and stabilizers (abstract, column 2, lines 28-46 and column 5, line 42 to column 6 line 12). The composition is formulated as tablets, capsules, granules, powders, syrups, injections (intravenous, intramuscular or subcutaneous for parenteral administration), suppositories and ointments (column 5, lines 30-36). Pharmaceutically acceptable vehicles are lactose, sucrose, mannitol, sorbitol, starch and starch derivatives, cellulose and cellulose derivatives (column 5, lines 42-55). Lubricants are magnesium stearate, calcium stearate, waxes and colloidal silica (column 5, lines 56-64). Binders include polyvinylpyrrolidone and macrogol and the compounds listed under vehicles (column 5, lines 65-67). Disintergrants may be the same as mentioned under vehicles, chemically modified starches and celluloses and bridged polyvinylpyrrolidone (column 6, lines 1-5). Phenols, benzalkonium chloride and propylparaben are the optional stabilizers (column 6, lines 6-12).

Although Tsujita does not specifically include cholestyramine in said composition, the prior art nonetheless discloses by reference that pravastatin and cholestyramine-containing composition is well known composition for lowering lipoprotein levels (column 1, lines 38-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Tsujita. One having ordinary skill in the art would have been motivated to prepare the composition of Tsujita and incorporate cholestyramine since pravastatin and cholestyramine can be combined since Tsujita's composition of HMG-CoA reductase inhibitor and insulin sensitizers is reported to show synergistic effect and better at treating arteriosclerosis. Determining the amounts of the parts of a composition is within the purview of

the skilled artisan to do and therefore obvious absent evidence in unexpected results to the contrary. The comprising language in the claims allows for other ingredients in the composition and future intended use is not critical in a composition claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
July 9, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600